K090815

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Name, Address, Phone and Fax Number of Applicant

Laurimed LLC
500 Arguello Street, Suite 100
Redwood City, CA 94063
Phone: (650) 587-5296
Fax: (650) 587-3823

MAY 21 2009

B. Contact Person

Sevrina Ciucci
Regulatory Affairs Consultant
(408) 316-4837

C. Date Prepared

March 20, 2009

D. Device Name

Trade Name:	Laurimed Discectomy System
Common Name:	Tissue Cutter/Aspirator
Classification Name:	Arthroscope (21 CFR §888.1100) Product Code HRX

E. Predicate Devices

The Laurimed Discectomy System is substantially equivalent to the Laurimed *Percutaneous Discectomy System* (K082194).

F. Device Description

The Laurimed Discectomy System is intended to be used to cut and aspirate nucleus material from discs in the spine. The system consists of a set of introduction tools (Dilator, Straight Cannula, Curved Cannula (qty. 2) and Trocar), a Device Cleaner, and a Discectomy Device

The Laurimed Discectomy System is supplied as a sterile, single patient use, single-level, disposable device.

G. Intended Use

The Laurimed Discectomy System is indicated for use in aspiration of disc material during open discectomies in the lumbar region of the spine.

H. Technological Comparison

The technological characteristics and principals of operation of the Laurimed Discectomy System are substantially equivalent to the noted predicate device.

I. Summary of Non-Clinical Data

Results of non-clinical testing demonstrated that the Laurimed Discectomy System is safe and effective for its intended use.

J. Summary of Data

The Laurimed Discectomy System has been carefully compared to a legally marketed device with respect to intended use and technological characteristics. In addition, non-clinical testing was conducted to validate the performance of the device and ensure the Laurimed Discectomy System functions as intended and meets design specifications. The comparison and non-clinical results demonstrate that the device is substantially equivalent to the predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2009

Laurimed, LLC
% Ms. Sevrina Ciucci
Regulatory Affairs Consultant
500 Arguello Street, Suite 100
Redwood City, California 94063

Re: K090815
Trade/Device Name: Discectomy System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: March 20, 2009
Received: March 25, 2009

Dear Ms. Ciucci:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

510(k) Number (if known): K 090815

Device Name: Discectomy System

Indications for Use:

The Laurimed Discectomy System is indicated for use in aspiration of disc material during open discectomies in the lumbar region of the spine.

Prescription Use X **OR** **Over-The-Counter Use**

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090815